IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF UTAH

LINDA P. SMITH, Plaintiff, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, Defendant.	)	Case No. 1:21-cv-47-HCN-DBP

REPLY IN SUPPORT OF DEFENDANT'S
CROSS-MOTION FOR SUMMARY JUDGMENT

The parties' cross-motions for summary judgment come before this Court in a somewhat unusual posture. As the Court is aware, plaintiff Linda Smith seeks review of a decision of the Medicare Appeals Council, which denied three claims for coverage under Medicare Part B. One claim concerned a MiniMed 630G system with Smartguard—a durable insulin pump that also functions as a continuous glucose monitor—while the others concerned disposable glucose sensors for use with that device. At the outset of this case, pursuant to Local Civil Rule 7-4(a)(2)(B), the Secretary of Health and Human Services confessed error as to all three claims. Because the insulin pump is durable medical equipment under the Medicare statute and regulations, the Appeals Council erred in denying coverage for that item. And its denial of coverage for the sensors was also in error, because the Appeals Council failed to consider an important aspect of the problem: whether the sensors were reasonable and necessary for the operation of the insulin pump function of the device, which uses their data to determine when to automatically shut off the flow of insulin.

The Secretary therefore urged this Court to enter judgment in favor of Mrs. Smith and remand for payment of the claim for the insulin pump, and determination of whether the sensors

should be covered as reasonable and necessary for the operation of the insulin pump. At the initial hearing in this case, the Secretary emphasized that remand proceedings would also allow the Appeals Council to consider the effect of a proposed rule (if finalized), under which the sensors would be covered by virtue of their role in the glucose-monitor function of the device (as opposed to its insulin-pump function). The Secretary continues to believe that judgment in Mrs. Smith's favor, on these grounds, followed by a remand for payment of one claim and reconsideration of the other two, would be an equitable resolution of this case.

If, however, this Court prefers to resolve the case on the basis of the arguments presented by the parties, then it should enter judgment in favor of the Secretary. Mrs. Smith has chosen not to pursue the Secretary's confession of error. And she has conspicuously declined to argue that the decision of the Appeals Council was substantively invalid, despite the fact that other litigants have prevailed on substantive challenges to similar decisions and the Secretary has proposed a rule that would adopt the view of those district courts. Instead, Mrs. Smith argues only that 1) an earlier decision in her favor at a lower level of administrative review should have precluded the Medicare Appeals Council from reaching the decision challenged here, and 2) an alleged *procedural* infirmity in the CMS Ruling on which the Appeals Council relied entitles Mrs. Smith to a *substantive* reversal of its decision, as well as vacatur of that Ruling. Those arguments fail for the reasons explained in the Secretary's cross-motion, and elaborated below.

ARGUMENT

A. Collateral estoppel did not preclude the challenged decision.

i. Because plaintiff never argued to the Medicare Appeals Council that the decision in ALJ Appeal No. 1-6020086584R1 should give rise to issue preclusion here, she failed to exhaust that issue and may not raise it now.

Mrs. Smith does not—and could not—deny that she may only seek judicial review of issues that she asked the Medicare Appeals Council to decide. As the Supreme Court has explained, "it is common for an agency's regulations to require issue exhaustion in administrative appeals." *Sims v. Apfel*, 530 U.S. 103, 108 (2000). "And when regulations do so, courts reviewing agency action regularly ensure against the bypassing of that requirement by refusing to consider unexhausted issues." *Id.* The regulations governing Medicare Appeals Council review provide that "[t]he request for review must identify the parts of the ALJ's . . . action with which the party requesting review disagrees and explain why he or she disagrees with the ALJ's . . . decision, dismissal, or other determination being appealed." 42 C.F.R. § 405.1112(b). And the regulations explain that "[t]he [Medicare Appeals] Council will limit its review of an ALJ's . . . actions to those exceptions raised by the party in the request for review, unless the appellant is an unrepresented beneficiary." *Id.* § 405.1112(c). Because Mrs. Smith was represented before the Appeals Council, the requirement of issue exhaustion applied to her.

But Mrs. Smith did not raise the issue that she now asks this Court to address: the allegedly preclusive effective of an administrative law judge's decision in an earlier appeal, No. 1-6020086584R1. Mrs. Smith's brief to the Appeals Council argued that *district court opinions to which Mrs. Smith was not a party* should collaterally estop the Appeals Council from denying coverage to her. AR 13–14. (She presented the same argument to the administrative law judge. AR 121–22.) Her brief never even mentioned the decision in ALJ Appeal No. 1-6020086584R1,

which Mrs. Smith now cites as the sole basis for collateral estoppel. Because Mrs. Smith did not point to ALJ Appeal No. 1-6020086584R1 in "explain[ing] why . . . she disagrees with the ALJ's . . . decision" in this case, 42 C.F.R. § 405.1112(b), and the Appeals "Council . . . limit[ed] its review . . . to those exceptions raised by the party in the request for review," *id.* § 405.1112(c), the Appeals Council did not consider whether the decision in ALJ Appeal No. 1-6020086584R1 precluded a contrary coverage determination here. As the Secretary explained in his cross-motion, because Mrs. Smith failed to exhaust that issue through the administrative process, she cannot raise it for the first time here.

Mrs. Smith argues that she did exhaust the issue. She says that, before the administrative law judge in this case, she "submitted ALJ Lambert's decision" in ALJ Appeal No. 1-6020086584R1 and, "relying on the Supreme Court's decision in *Astoria* [*Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104 (1991)], argued collateral estoppel." ECF No. 38 at 5 (Br. at 4). That is literally true, but misleading. Mrs. Smith "submitted ALJ Lambert's decision" as simply one among many ALJ and other administrative decisions in support of her position. *See* AR 1399–1742. She did not suggest that the decision in ALJ Appeal No. 1-6020086584R1 should affect the resolution of this case any differently than the other decisions that she submitted in a large batch. And "relying on the Supreme Court's decision in *Astoria*," Mrs. Smith "argued collateral estoppel"—but not on the basis of the decision in ALJ Appeal No. 1-6020086584R1. As she did before the Medicare Appeals Council, AR 13–14, Mrs. Smith argued for preclusion on the basis of district court decisions in favor of other litigants, AR 121–22. Because Mrs. Smith never argued to the Medicare Appeals Council (or even the administrative law judge in this case) that the earlier decision in ALJ Appeal No. 1-6020086584R1 should give rise to issue preclusion here, she did not exhaust the issue and may not raise it now.

Mrs. Smith also argues that, even if she failed to exhaust this issue through the administrative appeals process, she should nonetheless be able to present it here, because the Secretary did not plead her failure to exhaust as an affirmative defense. *See* Fed. R. Civ. P. 8(c)(1). That argument fails for two primary reasons. *First*, and most fundamentally, Rule 8 entitles the Secretary to "fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley v. Gibson*, 355 U.S. 41, 47 (1957); *see Warnick v. Cooley*, 895 F.3d 746, 751 (10th Cir. 2018). It is only fair notice that can trigger a defendant's obligation to plead defenses. And Mrs. Smith's complaint does not provide notice that issue preclusion (or collateral estoppel) is among the grounds on which her claims rest. Paragraphs 54 through 75 are the only section of the complaint that could conceivably be read to provide notice of a claim based on issue preclusion, and they merely make factual allegations about the proceedings in ALJ Appeal No. 1-6020086584R1. Nowhere in the complaint does Mrs. Smith assert that (as she now argues) the challenged decision was erroneous because the Medicare Appeals Council failed to give preclusive effect to the decision in ALJ Appeal No. 1-6020086584R1. The Secretary therefore had no obligation to plead Mrs. Smith's failure to exhaust that issue in the administrative appeals process.

Second, even if failure to exhaust an issue through the administrative process is an affirmative defense within the scope of Rule 8(c)(1), Mrs. Smith was not prejudiced by the absence of that affirmative defense from the Secretary's answer. The Tenth Circuit has cautioned that courts "must avoid hypertechnicality in pleading requirements and focus, instead, on enforcing the actual purpose of the rule." *Creative Consumer Concepts, Inc. v. Kreisler*, 563 F.3d 1070, 1076 (10th Cir. 2009) (quotation omitted). "Rule 8(c)'s ultimate purpose is simply to guarantee that the opposing party has notice of any . . . issue that may be raised . . . so that he or she is prepared to properly litigate it." *Id.* (quotation omitted). "When a plaintiff has notice that an affirmative

defense will be raised . . . , the defendant's failure to comply with Rule 8(c) does not cause the plaintiff any prejudice." *Id.* (quotation omitted). "And, when the failure to raise an affirmative defense does not prejudice the plaintiff, it is not error for the trial court to hear evidence on the issue." *Id.* (quotation omitted). As this Court is aware, the Secretary filed his amended answer on September 14, ECF No. 30, and his cross-motion for summary judgment on September 21, ECF No. 31. No conceivable prejudice could have attached in the span of that week. To the contrary, plaintiff had more than a month—until October 26—to respond to the Secretary's argument regarding issue exhaustion. This Court should therefore consider it, and resolve the issue of collateral estoppel on that basis. *See Ahmad v. Furlong*, 435 F.3d 1196, 1202 (10th Cir. 2006) (explaining that courts apply "the same standards that govern motions to amend when [they] determine whether the defendant should be permitted to 'constructively' amend the answer by [raising an affirmative defense] in the summary-judgment motion").

ii. The decision in ALJ Appeal No. 1-6020086584R1 does not give rise to issue preclusion here.

The decision in ALJ Appeal No. 1-6020086584R1, to which Mrs. Smith would accord preclusive effect, was the result of a one-party hearing, like the overwhelming majority of proceedings before administrative law judges in Medicare coverage cases. It could not practicably be otherwise: at any given moment, tens of thousands of Medicare appeals are pending before the agency's administrative law judges. *See, e.g.*, Status Report, Dkt. No. 103-1, *Am. Hosp. Ass'n v. Azar*, 14-cv-851 (D.D.C. Sept. 28, 2021) (approximately 86,000 pending ALJ appeals); 82 Fed. Reg. 4974, 4976 (Jan. 17, 2017) (noting that there were 650,000 pending ALJ appeals as of September 2016). As the Secretary explained in his cross-motion for summary judgment, such proceedings are generally not adversarial, and it is unsurprising that they do not give rise to issue preclusion. Were it otherwise, a Medicare beneficiary who lost an appeal before an ALJ and did

not seek further review could *never* obtain review of that issue by the Medicare Appeals Council or the federal courts. Such a rule would prejudice the rights of Medicare beneficiaries, and greatly complicate the already complex administration of Medicare claims by requiring the Secretary to track the outcome of hundreds of thousands of ALJ decisions, so that each of them could be afforded preclusive effect in future claims brought by that particular beneficiary. The Medicare statute simply does not require such a radical and detrimental revision of the administrative appeals process that the Secretary has been operating for more than fifteen years, without any congressional objection.

ALJ decisions regarding Medicare coverage claims lack preclusive effect. The Secretary's valid regulations make that clear. *See, e.g.*, 81 Fed. Reg. at 43,793 ("Individual determinations and decisions by . . . OMHA ALJs . . . are not precedential and have no binding effect on future initial determinations (and equivalent determinations) or claims appeals."). Two district courts have so held. *See Banks v. Azar*, 2021 WL 1759304, at *4 (N.D. Ala. Mar. 30, 2021) ("Based on the statutory and regulatory scheme of the Medicare Act, it is clear that application of collateral estoppel in Medicare matters runs counter to legislative intent and ALJ decisions should not be given preclusive effect."); *Christenson v. Azar*, 2020 WL 3642315, at *7 (E.D. Wis. July 6, 2020) ("Plaintiffs have failed to demonstrate that it is appropriate to apply the doctrine of collateral estoppel on the basis of ALJ-level decisions in the Medicare context."). And courts of appeals have noted that aspect of the Medicare appeals process. *See Porzecanski v. Azar*, 943 F.3d 472, 485 (D.C. Cir. 2019) (explaining that "ALJ decisions are non-precedential" for Medicare coverage claims); *W. Texas LTC Partners, Inc. v. Dep't of Health & Human Servs.*, 843 F.3d 1043, 1046 (5th Cir. 2016) ("[P]rior ALJ decisions are not binding on the DAB or other ALJs."). Mrs. Smith

barely acknowledges these cases, and neither distinguishes nor undermines them. *See* ECF No. 38 at 10 (Br. at 9).

Moreover, even if *some* ALJ decisions could have issue preclusive effect, collateral estoppel only results from an adversarial process, which the proceedings in ALJ Appeal No. 1-6020086584R1 were not. As the Supreme Court has explained, issue preclusion "is justified on the sound and obvious principle . . . that a losing litigant deserves no rematch after a defeat fairly suffered, in adversarial proceedings, on an issue identical in substance to the one he subsequently seeks to raise." *Astoria*, 501 U.S. at 107; *see* Restatement (Second) of Judgments § 27, cmt. a ("The rule of issue preclusion is operative where the second action is between the same persons who were parties to the prior action, *and who were adversaries . . . with respect to the particular issue* . . . ." (emphasis added)). Without an adversarial proceeding, it cannot be the case that "the party against whom the doctrine is invoked was *a party or in privity with a party* to the prior adjudication, and . . . had a *full and fair opportunity to litigate* the issue in the prior action." *Stan Lee Media, Inc. v. Walt Disney Co.*, 774 F.3d 1292, 1297 (10th Cir. 2014) (quoting *Murdock v. Ute Indian Tribe of Uintah & Ouray Reservation*, 975 F.2d 683, 687 (10th Cir. 1992)) (emphasis added in *Stan Lee*). The Supreme Court's decision in *Astoria* illustrates the sort of administrative proceeding that might ordinarily give rise to issue preclusion: an adversarial hearing between an employer and a terminated employee, "at which both parties were represented by counsel," followed by a decision on the existence of "probable cause to believe that petitioner had terminated respondent because of his age." 501 U.S. at 106. That is very far from the circumstances here, or in most administrative appeals of Medicare coverage claims.

Yet Mrs. Smith maintains that ALJ decisions in general, and ALJ Appeal No. 1-6020086584R1 in particular, should be accorded preclusive effect. Mrs. Smith argues that the

one-sided nature of such proceedings is no bar to preclusion because the Secretary theoretically *could* participate in the tens of thousands of ALJ appeals heard each year. In support of that position, she offers a single citation, to a Fifth Circuit case about the preclusive effect of a peculiar (and inapplicable) feature of Texas state law known as the "post-answer default judgment," which can be entered when a defendant answers the complaint but does not appear again. *See* ECF No. 38 at 19 (Br. at 18) (citing *In re Garner*, 56 F.3d 677, 680 (5th Cir. 1996)). That is obviously not the case here, and *Garner* does not (as Mrs. Smith seems to suggest) stand for any general principle that non-adversarial proceedings can give rise to issue preclusion so long as the participating party is put to a burden of proof. Mrs. Smith assumes that collateral estoppel should apply to ALJ decisions, and faults the Secretary for (as she says) attempting to deprive those decisions of preclusive effect by choosing not to appear. But that argument badly misreads the situation: the impossibility of actually litigating those many tens of thousands of ALJ proceedings through a meaningfully adversarial process is one important reason why issue preclusion ought not to attach to such decisions. *See Astoria*, 501 U.S. at 110 (explaining that the "suitability" of issue preclusion "may vary" according to the particular circumstances of the agency proceeding).

"The presumption" that Congress intends for administrative proceedings to have preclusive effect only applies "where Congress has failed expressly or impliedly to evince any intention on the issue." *Id.* It is a comparatively weak presumption: as the Supreme Court has explained, "administrative preclusion" does not "represent independent values of such magnitude and constancy as to justify the protection of a clear-statement rule." *Id.* at 109. Mrs. Smith is therefore wrong to suggest that this Court should determine whether the common law of collateral estoppel has been "abrogated" by the Medicare statute. ECF No. 38 at 11–16 (Br. at 10–15). The question is simply whether "Congress has . . . expressly or impliedly . . . evince[d] any intention on the

issue" of collateral estoppel with regard to ALJ decisions in Medicare appeals.[1] *Astoria*, 501 U.S. at 110.

The *Banks* court correctly concluded "that application of collateral estoppel in Medicare matters runs counter to legislative intent and ALJ decisions should not be given preclusive effect." 2021 WL 1759304, at *4. The *Banks* court noted that the Medicare statute instructs the Appeals Council, when "reviewing a decision on a hearing" held by an ALJ, to "review the case de novo." 42 U.S.C. § 1395ff(d)(2)(B); *see* 42 C.F.R. § 405.1100(c). Such an instruction, which clearly deprives ALJ decisions of any weight when reviewed directly by the Appeals Council, seems incompatible with a rule of preclusion that would have those same ALJ decisions (if not reviewed by the Appeals Council) resolve issues for a given beneficiary for all time—without any prospect for future consideration by the Appeals Council or the federal courts. *See Banks*, 2021 WL 1759304 at *4 ("To bind the Council to a decision of an [earlier] ALJ, the Council could not perform a de novo review that the statute and regulations require."). Mrs. Smith's allusions to other administrative review schemes do not defeat that basic point, as her attempts to overstate the presumption of administrative estoppel all but confess. *See* ECF No. 38 at 7–9 (Br. at 6–8); *supra* note 1.

As Mrs. Smith notes, the current statutory scheme for administrative appeals of Medicare claims was created in 2000. *See* Pub. L. No. 106-554, § 1(a)(6), 114 Stat. 2763 (enacting provisions at 114 Stat. 2763A-534 to 543). It was then amended in 2003. *See* Pub. L. No. 108-173, title IX, §§ 931(d), 932(a), 933(a)(1), (b), (c), (d)(1) to (3), 938(a), 940(a), (b)(1), 940A(a),

[1] Mrs. Smith attempts to bulk up this straightforward analysis with language from *BFP v. Resolution Trust Corp.*, 511 U.S. 531 (1994), and *United States v. Texas*, 507 U.S. 529 (1993), which adopt, for abrogations of the common law, the clear-statement rule rejected for questions of administrative estoppel in *Astoria*, 501 U.S. at 109.

948(b)(1), (c), 117 Stat. 2399, 2402 to 2406, 2413, 2416, 2417, 2426. Before those enactments, Medicare appeals were heard by the Social Security Administration. In September 1999 and January 2002, the HHS Office of the Inspector General (OIG) published reports on the Medicare appeals process, in anticipation of its potential transfer to CMS. The first report discussed the fact that "[p]recedence from prior cases is not considered [i]n ALJ hearings," and reviewed the "[n]on-adversarial nature of ALJ hearings." HHS OIG, Medicare Administrative Appeals: ALJ Hearing Process at 11, 13 (Sept. 1999), *available at* https://oig.hhs.gov/oei/reports/oei-04-97-00160.pdf. The second report similarly discussed the "[n]on-adversarial proceedings at each appeal level where the government, directly, or through its agents, is not a party to the appeal." HHS OIG, Medicare Administrative Appeals: The Potential Impact of BIPA at 5 (Jan. 2002), *available at* https://oig.hhs.gov/oei/reports/oei-04-01-00290.pdf. Neither report gave any indication that these non-adversarial ALJ hearings, to which the agency was not a party, would be accorded preclusive effect in future administrative proceedings (and in fact they were not). To the contrary, the reports described an administrative appeals process that was incapable of the documentation and communication necessary to apply issue preclusion. These OIG reports provide the best evidence of congressional knowledge of the Medicare appeals process, at the time of the 2000 and 2003 amendments to that process. *See also* Report to Congress, Plan for the Transfer of Respnsibility for Medicare Appeals (Mar. 2004), *available at* https://www.ssa.gov/legislation/medicare/medicare_appeal_transfer.pdf. In light of these reports, Congress's decision not to explicitly impose collateral estoppel on Medicare appeals can be fairly understood as "impliedly . . . evinc[ing] an[] intention" to continue the then-current practice of denying preclusive effect to such ALJ decisions. *Astoria*, 501 U.S. at 109. For that reason (among

others), the Secretary's regulations governing the Medicare Appeals Council are a valid implementation of the statute.

ALJ hearings on Medicare beneficiary claims have always been predominantly non-adversarial proceedings that do not give rise to collateral estoppel. That was true before Congress transferred authority over those proceedings to CMS, and it remained true after. Mrs. Smith's suggestion that Congress intended issue preclusion to apply to such ALJ decisions is entirely unpersuasive. If the Court reaches the merits of her collateral estoppel claim, it should be denied.

B. This Court cannot and should not vacate CMS Ruling 1682-R.

When CMS Ruling 1682-R was issued in January 2017, it required the coverage of certain CGM devices (but not others) as durable medical equipment, depending on whether the device could be used to make treatment decisions on the basis of its own readings, or required a further reading from a blood glucose monitor. In November 2020, the Secretary published a notice of proposed rulemaking which would, if finalized, "classify CGM systems . . . as DME" whether or not they can be used to make treatment decisions on the basis of their readings alone. 85 Fed. Reg. 70,358, 70,403–04 (Nov. 4, 2020). That proposed rule would supersede the CMS Ruling, if finalized, and in doing so would moot Mrs. Smith's claim for vacatur. Vacating the CMS Ruling before the finalization of the proposed rule would remove *both* the instruction that certain CGMs be covered *and* the instruction that other devices not be covered. Even if this Court could do so, it should not create such needless confusion when the Ruling is likely to be withdrawn shortly.

And the Court cannot do so, in any event. As the Secretary has argued, Mrs. Smith "cannot obtain vacatur of a CMS Ruling in a case for 'judicial review of the Secretary's final decision' on individual Medicare coverage claims." ECF No. 32 at 2 (quoting 42 U.S.C. § 1395ff(b)(1)(A)). Mrs. Smith contends that this argument is "foreclosed by . . . the Supreme Court's decision in

Bowen v. Michigan Academy of Family Physicians, 476 U.S. 667 (1986)," which "was brought under 42 U.S.C. § 1395ff(b) through 42 U.S.C. § 405(g)," "[j]ust like Mrs. Smith's suit in this case." ECF No. 37 at 4–5 (Br. at 3–4). But that is not true: *Michigan Academy* was not brought under 42 U.S.C. § 1395ff(b), which did not provide for such relief then, and does not provide for it now.

When the Medicare statute was first enacted in 1965, it "provided for only limited review of Part B decisions." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 16 (2000). Individuals could seek judicial review under § 1395ff(b) after a final determination of "entitlement under part A or part B," but the statute limited claims concerning the "amount of benefits" to Medicare Part A. Pub. L. No. 89-97, tit. 1, § 102(a), 79 Stat. 330, *codified at* 42 U.S.C. § 1395ff(b) (1970). A 1972 amendment maintained that differential treatment, albeit in different words. *See* Pub. L. No. 92-603, tit. II, § 290o(a), 86 Stat 1464, *codified at* 42 U.S.C. § 1395ff(b)(1) (1976). "Section 1395ff thus distinguishe[d] between two types of administrative decisions: eligibility determinations (that decide whether an individual is 65 or over or 'disabled' within the meaning of the Medicare program) and amount determinations (that decide the amount of the Medicare payment to be made on a particular claim)." *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982). "Conspicuously, the statute fail[ed] to authorize further review for determinations of the amount of Part B awards." *Id.* "In the context of the statute's precisely drawn provisions," the Supreme Court concluded that "this omission provides persuasive evidence that Congress deliberately intended to foreclose further review of such claims." *Id.*

In *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), however, the Supreme Court held "that Congress intended to bar judicial review *only* of determinations of the amount of benefits to be awarded under Part B," *id.* at 678 (emphasis added), and did not mean to

bar "challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves," *id.* at 675 (emphasis in original). The *Michigan Academy* Court therefore concluded that "an attack on the validity of a regulation is not the kind of administrative action that we described in *Erika* as an 'amount determination' which decides 'the amount of the Medicare payment to be made on a particular claim' and with respect to which the Act impliedly denies judicial review." *Id.* at 676 (quoting *Erika*, 456 U.S. at 208). The Court also held that 42 U.S.C. § 405(h), as applied to the Medicare program by § 1395ii, did not bar federal question jurisdiction over such challenges, because the contrary holding would have meant "no review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." *Id.* at 680.

After *Michigan Academy*, then, there were three approaches to judicial review of the Medicare Part B program. First, *eligibility* determinations could be challenged in federal court under 42 U.S.C. § 1395ff(b), after complying with the "rigorous scheme" of administrative presentment and exhaustion borrowed from § 405(g) and (h). *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130 (D.C. Cir. 1992). Second, "disputes over 'amounts' were (per statute) completely removed from judicial review." *Id.* (citing *Erika*). And third, "disputes over 'methodology' could be brought under 28 U.S.C. § 1331's provision for general federal question jurisdiction, subject only to conventional exhaustion requirements," and not the channeling requirements of § 405(g) and (h), as applied to the Medicare program by §§ 1395ff(b) and 1395ii. *Id.* (citing *Michigan Academy*). The third category—the *Michigan Academy* exception allowing for general federal question jurisdiction—consisted of claims that were neither *authorized* by § 1395ff(b) (*i.e.*, eligibility challenges) nor *barred* by the statute as it then existed (*i.e.*, amount disputes).

But § 1395ff(b) was amended several months after *Michigan Academy*, to eliminate the distinction between judicial review of Part A and Part B claims. Pub. L. No. 99–509, § 9341(a)(1)(B), *codified at* 42 U.S.C. § 1395ff(b)(1)(C) (1988); *see Nat'l Kidney*, 958 F.2d at 1132 (explaining that "the special treatment of part B, based on the pre-October 1986 statutory differences, cannot survive the elimination of those differences"). Because § 1395ff(b) now authorizes judicial review of many more Part B claims than it once did, the application of the *Michigan Academy* exception to Part B claims has been drastically restricted.

The Supreme Court synthesized its jurisprudence on judicial review of Medicare claims in *Illinois Council*. That case was brought under 28 U.S.C. § 1331, and claimed "that certain Medicare-related regulations violated various statutes and the Constitution." 529 U.S. at 5. The Court held that general federal question jurisdiction was unavailable, because the Medicare statute required those claims to be channeled through the administrative process. *Illinois Council* read *Michigan Academy* to hold that the Medicare statute applies the bar on general federal question jurisdiction set out in § 405(h) unless "application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Id.* at 19. Because review of the claims in *Illinois Council* was available through the administrative process, the Medicare statute required them to be properly channeled through that process. *Id.* at 25.

To summarize: *Michigan Academy* allowed general federal question jurisdiction for challenges to Medicare Part B regulations, because review through the administrative process was unavailable under § 1395ff(b) as it then stood. *Illinois Council* required the channeling of challenges to Medicare regulations whenever the administrative process allows for review. The very regulatory challenge brought in *Michigan Academy* would, therefore, now be subject to the

Medicare statute's requirement of channeling, because § 1395ff(b) now allows such Part B claims to be presented through the administrative process.

Recent discussions of the scope of judicial review in Medicare cases can be found in *American Hospital Association v. Azar*, 895 F.3d 822 (D.C. Cir. 2018), and *Porzecanski v. Azar*, 943 F.3d 472 (D.C. Cir. 2019). Those cases make clear that where the channeling requirement applies, then prospective relief such as vacatur is barred. Challenges to Medicare Part B coverage determinations have been subject to administrative channeling since § 1395ff(b) was amended (shortly after the decision in *Michigan Academy*), and so they no longer come within the exception described by *Michigan Academy*. Because "'all aspects' of any future [Medicare] claim 'must be channeled through the administrative process'" where such channeling is available, *Porzecanski*, 943 F.3d at 483 (quoting *Ill. Council*, 529 U.S. at 12), plaintiffs cannot obtain vacatur to prevent the Secretary from "denying future claims on [certain] grounds" in the future, *id.* at 480. Mrs. Smith's belated attempt to invoke mandamus jurisdiction does not change this analysis. *See* ECF No. 46 at 3 (Br. at 2) (citing 28 U.S.C. § 1361). Mrs. Smith has not even attempted to make out such a claim.

Finally, Mrs. Smith continues to insist that the alleged *procedural* failing in CMS Ruling 1682-R should lead this Court to issue a *substantive* ruling in her favor, despite the fact that she has obviously chosen to avoid raising any substantive objection to the decision of the Medicare Appeals Council. If the Court concludes that CMS Ruling 1682-R was not procedurally proper, then the correct course is to remand the case for a new determination without reference to that Ruling. Mrs. Smith's flat assertion that "no rational person could ever conclude" that she was not entitled to payment of the claims at issue here, ECF No. 37 at 7 (Br. at 6), is not a basis for this Court to overstep its limited role in providing judicial review of agency action.

CONCLUSION

If this Court chooses not to remand this case on the terms first suggested by the Secretary, it should enter summary judgment in favor of the Secretary.

Dated: November 9, 2021

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

MICHELLE BENNETT
Assistant Director, Federal Programs Branch

/s/ James Bickford
JAMES BICKFORD
Trial Attorney (N.Y. Bar No. 5163498)
United States Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW
Washington, DC 20530
James.Bickford@usdoj.gov
Telephone: (202) 305-7632
Facsimile: (202) 616-8470

Counsel for Defendant